



NDA 20-238/S-017

GlaxoSmithKline Consumer Healthcare  
Attention: Hannah Ochola  
Regulatory Affairs Manager, USRA  
1500 Littleton Road  
Parsippany, NJ 07054

Dear Ms. Ochola:

Please refer to your supplemental new drug application dated August 7, 2007, received August 7, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tagamet HB 200® (200 mg cimetidine) tablets.

We acknowledge receipt of your submission dated February 1, 2008.

This supplemental new drug application proposes a revised package insert, including removal of the questionnaire portion of the coupon included in the insert.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed package insert submitted February 1, 2008, and must be formatted in accordance with the applicable requirements of 21 CFR 201.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-238/S-017.**" Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Geri Smith, Regulatory Project Manager, at [geri.smith@fda.hhs.gov](mailto:geri.smith@fda.hhs.gov) or (301) 796-2204.

Sincerely,

*{See appended electronic signature page}*

Andrea Leonard-Segal, M.D.  
Director  
Division of Nonprescription Clinical Evaluation  
Office of Nonprescription Products  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Andrea Segal

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